

Message Text

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SUBJECT: PENDING U.S. BAN ON USE OF SACCHARIN IN FOOD AND
BEVERAGES

REF: STATE 55170

1. FOLLOWING IS FDA NEWS RELEASE ON PENDING BAN ON
SACCHARIN MENTIONED IN REFTEL. BEGIN TEXT:

"THE FOOD AND DRUG ADMINISTRATION ON MARCH 9 ANNOUNCED IT
INTENDS TO PROHIBIT USE OF SACCHARIN IN FOODS AND BEVERAGES
BECAUSE THE ARTIFICIAL SWEETENER HAS CAUSED MALIGNANT
BLADDER TUMORS IN TEST ANIMALS.

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DOCUMENTS PROPOSING THE BAN WILL BE PUBLISHED IN THE
FEDERAL REGISTER AS SOON AS THEY CAN BE PREPARED (30 DAYS
OR LESS).

SACCHARIN IS THE ONLY ARTIFICIAL SWEETENER CURRENTLY
APPROVED FOR USE IN THE UNITED STATES. AT LEAST FIVE

MILLION POUNDS A YEAR ARE USED IN FOOD, ABOUT THREE-QUARTERS IN DIET SODAS AND THE REMAINDER IN DIETETIC FOODS AND AS A TABLE TOP SWEETENER IN PLACE OF SUGAR.

THE DECISION TO PROHIBIT USE OF SACCHARIN WAS TAKEN AFTER CAREFUL CONSULTATION WITH THE HEALTH PROTECTION BRANCH OF THE CANADIAN GOVERNMENT. THE ACTION IS BASED ON TWO FACTORS:

-- A STUDY SPONSORED BY THE CANADIAN GOVERNMENT SHOWED THAT SACCHARIN, WHEN FED IN HIGH DOSES TO RATS, CAUSED MALIGNANT BLADDER TUMORS. FDA OBTAINED PRELIMINARY RESULTS OF THE STUDY AT A MEETING MARCH 7 IN OTTAWA WITH CANADIAN SCIENTISTS. CANADA IS TAKING ACTION SIMILAR TO THAT BEING ANNOUNCED BY FDA.

-- THE SO-CALLED "DELANEY CLAUSE" OF THE FOOD, DRUG AND COSMETIC ACT PROHIBITS THE USE IN FOOD OF ANY INGREDIENT SHOWN TO CAUSE CANCER IN ANIMALS OR MAN.

SHERWIN GARDNER, ACTING COMMISSIONER OF FOOD AND DRUGS, SAID: "PREVIOUS ANIMAL TESTS HAVE NOT DEMONSTRATED WITH ANY DEGREE OF CERTAINTY WHETHER SACCHARIN COULD CAUSE CANCER. BUT THESE CANADIAN TESTS SHOW UNEQUIVOCALLY THAT THIS SUBSTANCE CAN PRODUCE MALIGNANT BLADDER TUMORS IN RATS.

"THE LAW IS EQUALLY CLEAR. IT SAYS THAT NO INGREDIENT THAT CAUSES CANCER IN MAN OR ANIMALS MAY BE ADDED TO OUR UNCLASSIFIED

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FOOD SUPPLY."

"SCIENCE AND LAW DICTATE THAT SACCHARIN BE REMOVED FROM OUR FOOD SUPPLY."

MR. GARDNER CONTINUED: "SACCHARIN HAS BEEN IN USE FOR MORE THAN 80 YEARS AND HAS NEVER BEEN KNOWN TO HARM PEOPLE, AND SINCE THE CANADIAN DATA DO NOT INDICATE AN IMMEDIATE HAZARD TO PUBLIC HEALTH, WE DO NOT CONSIDER THE RECALL OF EXISTING PRODUCTS TO BE NECESSARY. WE, NEVERTHELESS, ENCOURAGE MANUFACTURERS TO DISCONTINUE USE OF SACCHARIN AS SOON AS POSSIBLE, EVEN WHILE WE ARE DRAFTING THE DOCUMENTS NEEDED TO ACCOMPLISH THIS ACTION.

"CONSUMERS WHO WANT TO AVOID SACCHARIN IN THE INTERIM MAY DO SO, SINCE FDA REQUIRES THAT ALL PRODUCTS CONTAINING SACCHARIN MUST LIST IT ON THE LABEL."

IN THE CANADIAN STUDY, 50 MALE RATS AND 50 FEMALE RATS

WERE FED 5 PERCENT SACCHARIN IN THEIR DIETS. THREE MALES AND NO FEMALES DEVELOPED MALIGNANT BLADDER TUMORS.

IN ADDITION, 50 FEMALE AND 50 MALE OFFSPRING OF THESE

RATS WERE FED SACCHARIN. TWO FEMALE AND 12 MALE RATS DEVELOPED BLADDER TUMORS.

THUS, OF A TOTAL OF 200 RATS, 17 DEVELOPED MALIGNANT BLADDER TUMORS.

IN CONTRAST, OF 100 "CONTROL ANIMALS" -- THOSE NOT FED SACCHARIN -- ONLY TWO DEVELOPED TUMORS.

THE DOSAGES OF SACCHARIN FED THE RATS IN THE CANADIAN STUDY WERE IN EXCESS OF THE AMOUNT THAT A CONSUMER WOULD RECEIVE FROM DRINKING EIGHT-HUNDRED (800) 12 OZ. DIET UNCLASSIFIED

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SODAS DAILY OVER A LIFETIME.

AS PART OF THE TEST, SCIENTISTS TRIED TO LEARN WHETHER AN IMPURITY IN SACCHARIN CALLED ORTHO-TOLUENESULFONAMIDE (OTS) MIGHT HAVE BEEN RESPONSIBLE FOR EARLIER SUSPICIONS THAT SACCHARIN COULD CAUSE CANCER. NO TUMORS WERE FOUND IN RATS FED OTS. THE STUDIES, THEREFORE, INDICATE THAT SACCHARIN, NOT OTS, WAS RESPONSIBLE FOR ADVERSE EFFECTS IN THE RATS.

THE CANADIAN STUDY WAS UNDERTAKEN IN FEBRUARY 1974 IN AN EFFORT TO PROVIDE A DEFINITE ANSWER ON WHETHER SACCHARIN COULD CAUSE CANCER. STUDIES CONDUCTED EARLIER BY FDA AND OTHERS RAISED QUESTIONS ABOUT THE CANCER-CAUSING POTENTIAL OF THE ARTIFICIAL SWEETENER, BUT A NATIONAL ACADEMY OF SCIENCES/NATIONAL RESEARCH COUNCIL EVALUATION OF ALL EARLIER STUDIES CONCLUDED IN 1974 THAT FURTHER RESEARCH WAS NEEDED.

SINCE 1972, FDA HAS IMPOSED LIMITS ON SACCHARIN USE. THE INTENT OF THOSE LIMITATIONS WAS TO DISCOURAGE GENERAL USE BY CONSUMERS OF SACCHARIN AND TO PREVENT AN INCREASE IN ITS USE.

FDA DOES NOT PERMIT THE SALE OF ANY ARTIFICIAL SWEETENER OTHER THAN SACCHARIN. CYCLAMATE WAS BANNED IN 1970. ITS MANUFACTURER, ABBOTT LABORATORIES, SUBSEQUENTLY PETITIONED FOR RECONSIDERATION OF THAT BAN. FDA DENIED THE PETITION, CONCLUDING THAT THERE WAS INSUFFICIENT EVIDENCE TO DEMONSTRATE THAT CYCLAMATE WAS SAFE. FDA RECENTLY GRANTED ABBOTT AND THE CALORIE CONTROL COUNCIL

A HEARING ON THE DENIAL. A PREHEARING CONFERENCE IS SCHEDULED FOR APRIL 20.

ANOTHER ARTIFICIAL SWEETENER, ASPARTAME, WAS APPROVED BY FDA IN 1974 BUT HAS NEVER BEEN MARKETED. FDA STAYED ITS UNCLASSIFIED

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APPROVED FOR ASPARTAME IN DECEMBER, 1975, AFTER AN

AUDIT OF THE SAFETY DATA SUBMITTED BY THE MANUFACTURER, G.D. SEARLE & COMPANY, REVEALED DISCREPANCIES. FDA IS NOW REVIEWING ASPARTAME TO SEE WHETHER ITS APPROVAL SHOULD BE REINSTATED OR PERMANENTLY REVOKED. IN THE MEANTIME IT MAY NOT BE SOLD." END TEXT.

2. IN ADDITION TO DRAWING ON THE ABOVE MR. GARDNER MADE THE FOLLOWING STATEMENTS IN HIS PRESS RELEASE. BEGIN TEXT:

"THE FOOD AND DRUG ADMINISTRATION WILL BEGIN IMMEDIATELY THE LEGAL PROCESS NECESSARY TO END THE USE OF SACCHARIN IN OUR FOODS AND BEVERAGES. THIS PROCESS WILL BEGIN WITH PREPARATION OF A PROPOSED SUSPENSION ORDER TO BE ISSUED IN 30 DAYS OR SOONER. -

THE FDA PROPOSAL WILL ALLOW 60 DAYS FOR PUBLIC COMMENT AND REACTION. AN INFORMAL TWO-DAY PUBLIC HEARING BEFORE THE COMMISSIONER WILL BE HELD DURING THE COMMENT PERIOD.

THE DATES FOR PUBLICATION OF THE PROPOSAL AND FOR THE PUBLIC HEARING WILL BE ANNOUNCED SHORTLY. A FINAL ORDER WILL BE ISSUED AFTER EVALUATING THE COMMENTS; WE CANNOT PREDICT TESTS DATA WITH CERTAINTY, BUT IT COULD BE AS EARLY AS 90 DAYS FROM THE PROPOSAL, GIVEN THE PROCEDURAL STEPS INVOLVED. - --- -

THIS PROPOSED ACTION CLIMAXES MANY YEARS OF SCIENTIFIC INQUIRY BY THE FOOD AND DRUG ADMINISTRATION AND MANY OTHERS TO DETERMINE WHETHER THERE IS A HEALTH RISK FROM SACCHARIN, THE ONLY NON-NUTRITIVE SWEETENER NOW MARKETED IN THE UNITED STATES. -

WE WOULD LIKE THE AMERICAN PUBLIC TO UNDERSTAND THAT THIS UNCLASSIFIED

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ACTION IS BASED ON SCIENCE AND ON REQUIREMENTS OF FEDERAL

LAW. WE HAVE NOT CONCLUDED THAT SACCHARIN IS AN IMMEDIATE HAZARD TO HUMAN HEALTH. THE SAME JUDGMENT HAS BEEN REACHED BY CANADIAN SCIENTISTS AND GOVERNMENT OFFICIALS. WE HAVE NO EVIDENCE THAT SACCHARIN HAS EVER CAUSED CANCER IN HUMAN BEINGS. BUT WE DO NOW HAVE CLEAR EVIDENCE THAT THE SAFETY OF SACCHARIN DOES NOT MEET THE STANDARDS FOR ADDITIVES ESTABLISHED BY CONGRESS.

SUCH EVIDENCE HAS BEEN SLOW IN COMING. AT LEAST 40 STUDIES IN ANIMAL TEST LABORATORIES THROUGHOUT THE WORLD HAVE PURSUED THE QUESTION OF SACCHARIN SAFETY DURING A DECADE OF RESEARCH.

UNTIL TODAY, THE RESULTS OF THESE STUDIES HAD FAILED TO GIVE US A CLEAR ANSWER. BUT DEFINITIVE EVIDENCE FROM THE NEW CANADIAN STUDY NOW LEAVES NO DOUBT THAT SACCHARIN DOES CAUSE BLADDER TUMORS AND OTHER ADVERSE EFFECTS IN RATS.

WITH THIS EVIDENCE IN HAND, THE FDA IS NOW BOUND TO TAKE ACTION BY THE MOST UNEQUIVOCAL REQUIREMENT OF THE U.S. FOOD, DRUG, AND COSMETIC ACT. THE DELANEY CLAUSE STATES VERY SIMPLY THAT ANY INGREDIENT THAT CAUSES CANCER WHEN FED TO TEST ANIMALS IN PROPER TESTS MAY NOT BE APPROVED FOR USE IN THE AMERICAN FOOD SUPPLY.

WE ASK THAT THESE POINTS BE CONSIDERED BY THE AMERICAN PEOPLE.

FIRST, SACCHARIN IS BUT ONE OF A NUMBER OF PRODUCTS THE FDA HAS ACTED AGAINST OR MAY BE REQUIRED TO ACT AGAINST IN THE MONTHS AND YEARS AHEAD. AS SCIENCE BECOMES MORE SOPHISTICATED, WE WILL INCREASINGLY FIND THAT SOME OLD AND TRUSTED FRIENDS IN OUR FOODS AND DRUGS MAY NOT BE AS INNOCENT AS WE HAD THOUGHT. SACCHARIN APPARENTLY IS UNCLASSIFIED

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A GOOD EXAMPLE. THE FOOD COLORS RECENTLY REMOVED BY FDA OFFER ANOTHER.

SECOND, WHILE SACCHARIN MAY MAKE FOODS A LITTLE MORE PALATABLE FOR THE INDIVIDUAL ON A WEIGHT REDUCTION DIET, WEIGHT CONTROL CAN BE MAINTAINED WITH MANY DIFFERENT DIETS WITHOUT THE USE OF SACCHARIN." END TEXT.

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